



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,821	10/19/2001	Jane Werling	IDD-5657 CIP2	2470

7590

11/04/2003

MARK J. BUONAIUTO, ESQ.
BAXTER INTERNATIONAL INC.
LAW DEPARTMENT
ONE BAXTER PARKWAY, DF2-2E
DEERFIELD, IL 60015

EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/04/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,821

Applicant(s)

WERLING ET AL.

Examiner

Simon J. Oh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicants' amendment, response, and petition for extension of time, all received on 13 August 2003.

Double Patenting

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The provisional rejection of Claims 1-29, 65, and 66 under 35 U.S.C. 101 over Claims 98-128 of copending Application No. 10/021,692 is hereby withdrawn.

The provisional rejection of Claim 1 under 35 U.S.C. 101 over Claim 119 of copending Application No. 09/953,979 is hereby withdrawn.

The provisional rejection of Claims 30-40 under the judicially created doctrine of double patenting over Claims 98-126 of co-pending Application No. 10/021,692 is maintained.

Claims 1-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 98-126 of copending Application No. 10/021,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because there exists a substantial overlap of scope in the method steps recited in the claims.

Art Unit: 1615

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 1 under 35 U.S.C. 112, second paragraph is hereby withdrawn.

The rejection of Claim 65 under 35 U.S.C. 112, second paragraph, is rendered moot with the cancellation of that claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-64 under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* in view of Cima *et al.* is maintained.

The rejection of Claims 65 and 66 under 35 U.S.C. 103(a) as being unpatentable over Stainmesse *et al.* in view of Cima *et al.* is rendered moot with the cancellation of that claim.

Response to Arguments

Applicant's arguments filed 13 August 2003 have been fully considered but they are not persuasive.

Regarding the current rejection of double patenting in the instant application, although the applicants have amended Claim 1 to recite different method steps, there still exists such a significant overlap in the scope of the instant claims, such that they are still not patentably distinct from the Claims in the 10/021,692 application. Hence, the instant claims will remain rejected for double patenting.

The disclosure in the Stainmesse *et al.* patent in which the mixture of the two liquid phases is subjected to moderate stirring is considered by the examiner to read on the applicants' claim limitation of adding energy to a pre-suspension (See Column 2, Lines 43-46). Without any further definition of the type of energy to be added to the pre-suspension in those instant claims that are broad, the step of moderate stirring disclosed in the prior art is interpreted by the examiner to be a step of adding mechanical energy to a pre-suspension. Furthermore, the applicants have taken a narrow interpretation of the prior art. At the most, the prior art passages cited by the applicants disclose embodiments that may be non-preferred, rather than inoperable altogether. As such, the examiner does not see within the disclosure of the prior art a statement that specifically bars the use of an energy-addition step.

The examiner does not consider the indomethacin example cited by the applicants in the prior art to be particularly limiting to the scope of the disclosure of the methods of the prior art. As the methods of the prior art can be applied to various substances, it is the position of the examiner that the state of the particles (crystalline or non-crystalline) produced by the prior art depend upon, or are influenced by the nature of the substance to be made into sub-micron particles. Absent a demonstration made by the applicants showing otherwise, the examiner will not

Art Unit: 1615

consider the scope of the methods of the prior art to be limited solely to the production of non-crystalline particles for all substances disclosed therein.

Accordingly, since the examiner does not interpret the disclosure of the Stainmesse *et al.* patent to be strictly limited in scope to the manufacture of non-crystalline particles, the rejection based upon the combination of disclosures from that reference with the Cima *et al.* patent is deemed proper and is maintained. The claims will remain rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1615

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
